IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

IN RE: SMITH & NEPHEW BIRMINGHAM HIP RESURFACING (BHR) HIP IMPLANT PRODUCTS LIABILITY LITIGATION	MDL-17-md-2775 Master Docket No. 1:17-md-2775 JUDGE CATHERINE C. BLAKE
DEBRA D. WILSON, Plaintiff, vs. SMITH & NEPHEW, INC., Defendant.	**DIRECT-FILED THA COMPLAINT PURSUANT TO CASE MANAGEMENT ORDER NO. 7** **THA TRACK CASE** Civil Action No.: 1:18-cv-2545

COMPLAINT AND JURY DEMAND

This is a product liability lawsuit relating to the recalled Smith & Nephew R3 metal-on-metal total hip arthroplasty system, which was designed, manufactured, promoted and distributed in the U.S. by Defendant Smith & Nephew, Inc. Plaintiff, Debra D. Wilson, states the following for her complaint:

PARTIES, JURISDCITION AND VENUE

1. Plaintiff, Debra D. Wilson ("Wilson"), at all times relevant to this action, was a citizen and resident of Laurel, Prince George's County, Maryland, which is part of the District of Maryland, U.S. District Court.

2. Smith & Nephew, Inc. ("Smith & Nephew"), is a foreign corporation organized and existing under the laws of Tennessee. It does substantial business in the State of Maryland and within the District of Maryland. Smith & Nephew designs and manufactures medical devices for use in hip replacement and resurfacing procedures. It is a global medical technology company,

with its headquarters in England, a presence in more than 90 countries worldwide, and total sales of $4.8 billion in 2017. Its domestic headquarters are in Memphis, Tennessee.

3. Smith & Nephew has purposefully directed its activities towards, and derived substantial profits from, the State of Maryland. Defendant had the requisite minimum contacts with the State of Maryland, and the amount in controversy in this action exceeds Seventy Five Thousand Dollars ($75,000.00) exclusive of interest and costs.

4. Defendant, Smith & Nephew designed, tested, manufactured, assembled, inspected, imported, distributed, and/or sold the R3 system and its component parts described below with the intention, expectation, and purpose that it would be distributed through the chain of commerce and that it would be ultimately sold and used in the State of Maryland. Thus, Defendant had the requisite minimum contacts with the State of Maryland, and complete diversity of citizenship exists pursuant to 28 U.S.C. § 1332.

5. Venue is proper in this division and district pursuant to 28 U.S.C. § 1391(b)(2) because a substantial part of the events or omissions giving rise to the claim occurred in this division and district, and because Plaintiff seeks to recover an amount in excess of $75,000.00, exclusive of interest and costs.

FACTUAL BACKGROUND

Design, Regulation, and Marketing of the R3 Acetabular System

6. On or about June 14, 2006, Smith & Nephew received Sec. 510(k) approval from the FDA to market its Class II REFLECTION 3-Hole Acetabular Shell ("R3 Shell"). The 510(k) regulatory process is a "limited form of review" pursuant to 21 U.S.C. §360(k), and acts as an easier alternative to the traditional Premarket Approval ("PMA") process. The more lenient 510(k) alternative does not convey representations about safety or effectiveness, and does not require

clinical studies or other extensive testing. Instead, it is based on "substantial equivalence" to an earlier approval for a different device or devices, which are called the predicate device(s).

7. One year later, on or about June 6, 2007, Smith & Nephew received 510(k) approval for the full Reflection 3 ("R3") Acetabular system, including the previously approved R3 shell, and a liner made of cross-linked polyethylene. The shell and liner were intended to be used in connection with a femoral head made of cobalt and chrome, and a traditional femoral stem which is inserted into the femur, or thigh bone.

8. In November 2008, Smith & Nephew received approval from the FDA to market an optional metal liner with the R3 system, an as alternative to the polyethylene liner. The approval for the optional metal liner was considered by the FDA as an extension to a previous PMA granted in May 2006 for the Birmingham Hip Resurfacing System ("BHR System"). The new liner was known as the R3 metal liner.

9. By February of 2009, Smith & Nephew was marketing and promoting the R3 metal liner for use with the R3 Acetabular System, notwithstanding the fact that the R3 was only approved for use with the BHR system. Indeed, in February of 2009, Smith & Nephew issued a press release announcing "the introduction of a metal liner option for its R3 Acetabular System." In doing so, Smith & Nephew made representations that the R3 metal liner was safe and effective when used as part of a total hip replacement device in combination with its R3 acetabular component and cobalt chrome femoral heads and sleeves. For example, in the press release Smith & Nephew's president of orthopaedics, Joseph DeVivo, hailed the arrival of the R3 metal liner as proof of the company's position as a "leading innovator" in the industry.

10. In June 2012, Smith & Nephew issued a recall for the optional metal liner, even though it was only approved for use with the BHR system. The company's announcement,

published on the FDA's website, stated that the reason for the recall was a higher than expected revision rate for patients. Smith & Nephew issued the recall only after receiving numerous letters from the FDA warning the company not to sell the metal liner for use in total hip replacement surgeries, and instead to restrict the liner to the BHR resurfacing system. The recall announcement also told patients and surgeons that the standard of care was not changing for the approximately 7,700 individuals already implanted with the metal liner.

11. At all times mentioned herein, the R3 acetabular component, when used in combination with a metal liner, has been linked to complications, including, but not limited to, the accelerated release of metal debris and ions into the body / blood stream requiring revision surgery.

12. At all times mentioned herein, Defendants' femoral heads and femoral head sleeves made from cobalt chrome materials have been linked to complications, including, but not limited to, the accelerated release of metal debris and ions into the body / blood stream requiring revision surgery when used in combination with a metal liner.

PLAINTIFF'S INJURIES

13. On or about September 15, 2009, Plaintiff underwent a right total hip replacement using the R3 acetabular system with an optional metal liner. The surgery was performed by Dr. Scott Marwin at NYU Hospital for Joint Diseases in New York City, New York.

14. The device that was implanted into Plaintiff's right hip consisted of the following component parts, all of which were designed and manufactured by Smith & Nephew: (1) an R3 acetabular cup; (2) a cobalt chrome femoral head; (3) a cobalt chrome femoral head sleeve; (4) an Anthology stem; and (4) an R3 metal liner. This system was a metal-on-metal hip implant.

15. Dr. Marwin was aware of Smith & Nephew's marketing and promotional activities for the optional R3 metal liner for use in combination with its R3 acetabular component and cobalt

chrome femoral heads and sleeves, despite the lack of FDA approval for the components being used together.

16. Upon information and belief, a Smith & Nephew sales representative was present during Plaintiff's surgery and selected and recommended that Dr. Marwin implant the R3 metal liner device together with the other component parts of the R3 system, despite the lack of FDA approval for these components to be used together. In doing so, the sales representative made representations that the component parts of the device would combine to make a high-quality, safe and effective hip replacement system.

17. On or about July 11, 2018, after conservative measures to treat Plaintiff's hip pain and other negative symptoms were not successful, Plaintiff underwent right revision surgery in order to remove the defective, recalled, and unreasonably dangerous R3 acetabular system. Plaintiff's revision surgery was performed by Dr. Paul J. King at Anne Arundel Medical Center in Annapolis, Maryland due to indicia of metallosis and increasingly elevated cobalt and chromium levels.

18. Because the R3 acetabular system with the optional metal liner is not approved by the FDA, its safety and efficacy are difficult to study. However, the system suffers from many of the same problems that plague other metal-on-metal hips. For example, data from the Australian Orthopaedic Association's National Joint Registry shows a revision rate of 2.48 per 100 years, more than triple the rate of 0.79 for all primary total hip replacements. Similarly, the United Kingdom's National Joint Registry shows a revision rate for the R3 system of 6.3 percent at 4 years, compared to just 2.89 percent for all other hip systems.

19. The R3 acetabular system is prone to premature failure in part because metal ions created by the metal components rubbing together entered the patient's bloodstream, destroy

tissue, create an adverse reaction and cause the system to fail and require revision. The metal ions produced by the R3 system include metal ions from the cup and from the femoral head placed inside that cup, along with the optional metal liner.

20. It was the duty of Defendant Smith & Nephew, Inc. to comply with all applicable FDA regulations, including the requirements of both the 510(k) process and the PMA process. Notwithstanding this duty, Smith & Nephew violated these requirements in one or more of the following ways, as evidenced by the conduct described above, among other conduct:

a. Failed to submit a PMA supplement for the optional metal liner for review and approval by the FDA. 21 C.F.R.§814.39;

b. Defendant Smith & Nephew sold, distributed and permitted use of its R3 metal liner in violation of the regulations prescribed under 21 U.S.C. §360j(e). 21 U.S.C. § 352(q);

c. Failed to restrict the use of the optional metal liner with the BHR system, and instead promoted the unapproved use of the liner with other components in the R3 family that are not PMA approved. 21 U.S.C. §352(r);

d. Failed to comply with the requirements of 21 U.S.C. §§§ 360h, 360i, and 360l;

e. Failed to implement a proper training course for surgeons using the R3 metal liner as required by the original PMA Order and in violation of the Act;

f. Failed to properly train surgeons using the R3 metal liner on the permitted use of the device system and its respective component parts and failed to properly train and/or instruct surgeons on what products/devices surgeons could and/or could not use in a total hip arthroplasty; and/or

g. Failed to conduct post-approval clinical studies of the R3 metal liner and failed to report adverse events involving the R3 metal liner to the FDA, including revision surgeries.

COUNT ONE: STRICT PRODUCTS LIABILITY

21. Plaintiff reasserts, realleges and incorporates all other paragraphs in the Complaint as if fully set out herein.

22. At all times relevant to Plaintiff's claims, Smith & Nephew was engaged in the business of designing, manufacturing, assembling, testing, inspecting, marketing, distributing, and/or selling hip replacement devices throughout the United States, including the State of Maryland, for use by the general public for profit.

23. Defendant designed, manufactured, promoted, assembled, tested, inspected, marketed, imported, distributed, and/or sold the R3 acetabular system with an optional metal liner, that was implanted into Plaintiff.

24. At the time the R3 system components were implanted into Plaintiff, there was no unforeseeable substantial change to the components from the time they left the possession of Defendant until they reached Plaintiff, the ultimate user or consumer. To the contrary, the device was in substantially the same condition when it was implanted into Plaintiff as when it left the possession of Defendant.

25. At all times material to this Complaint, the device was in a defective and unreasonably dangerous condition. Such condition included, but is not limited to, one or more of the following particulars:

a. the device contained manufacturing defects, subjecting Plaintiff and others to risks, including, but not limited to, painful surgery to remove and replace the defective product;

b. the device contained unreasonably dangerous design defects and was not reasonably safe when used in a foreseeable manner, subjecting Plaintiff and others to risks, including, but not limited to, painful surgery to remove and replace the defective product;

c. the device was insufficiently tested;

d. the device was not accompanied by adequate instructions and/or warnings

to fully inform Plaintiff or her physician of the full nature or extent of the risks associated with its use;

e. the device was improperly designed, manufactured, assembled, tested, inspected, promoted, marketed, distributed, and/or sold in violation of the Federal Food, Drug, and Cosmetic Act ("FDCA" or "Act") and FDA regulations; and,

f. the device was improperly designed, manufactured, assembled, tested, inspected, promoted, marketed, distributed, and/or sold without approval as required by and in violation of the FDCA and FDA regulations.

28. At all times material to this Complaint, the R3 acetabular component, cobalt chrome femoral head and femoral head sleeve implanted into Plaintiff were in a defective and unreasonably dangerous condition. Such condition included, but is not limited to, one or more of the following particulars:

a. the R3 acetabular component, optional metal liner, cobalt chrome femoral head and femoral head sleeve contained manufacturing defects, subjecting Ms. Wilson and others to risks, including, but not limited to, painful surgery to remove and replace the defective product;

b. the R3 acetabular component, optional metal liner, cobalt chrome femoral head and femoral head sleeve contained unreasonably dangerous design defects and was not reasonably safe when used in a foreseeable manner, subjecting Ms. Wilson and others to risks, including, but not limited to, painful surgery to remove and replace the defective product;

c. the R3 acetabular component, optional metal liner, cobalt chrome femoral head and femoral head sleeve were insufficiently tested;

d. the R3 acetabular component, optional metal liner, cobalt chrome femoral head and femoral head sleeve were not accompanied by adequate instructions, warnings and labels, including, but not limited to, instructions, warnings and labels regarding the risks and dangers of using the R3 acetabular component, cobalt chrome femoral head and femoral head sleeve in combination with a metal liner;

e. the R3 acetabular component, optional metal liner, cobalt chrome femoral head and femoral head sleeve were not accompanied by adequate instructions, warnings and labels indicating that the R3 acetabular component, cobalt chrome femoral head and femoral head sleeve should not

be used in combination with a metal liner;

f. the R3 acetabular component, optional metal liner, cobalt chrome femoral head and femoral head sleeve were improperly promoted, marketed and sold to be used in combination with a metal liner;

g. the R3 acetabular component, optional metal liner, cobalt chrome femoral head and femoral head sleeve were improperly promoted, marketed and sold to be used in combination with the R3 metal liner in violation of the FDCA and FDA regulations; and,

h. the R3 acetabular component, optional metal liner, cobalt chrome femoral head and femoral head sleeve were improperly promoted, marketed and sold when Defendant had failed to comply with the FDA's post-marketing surveillance obligations.

29. At all times material to this Complaint, the R3 metal liner implanted into Plaintiff was in a defective and unreasonably dangerous condition. Such condition included, but is not limited to, one or more of the following particulars:

a. the R3 metal liner contained manufacturing defects, subjecting Plaintiff and others to risks, including, but not limited to, painful surgery to remove and replace the defective product;

b. the R3 metal liner contained unreasonably dangerous design defects and was not reasonably safe when used in a foreseeable manner, subjecting Plaintiff and others to risks, including, but not limited to, painful surgery to remove and replace the defective product. These defects include a higher in vivo wear rate, measured both volumetrically and in linear wear, compared to Defendant's expected wear rate based on machine tests;

c. the R3 metal liner was insufficiently tested with the other R3 components, because it was only approved for use with the separate BHR system;

d. the R3 metal liner was not accompanied by adequate instructions, warnings and/or labels for use with the other R3 components, because it was only approved for use with the separate BHR system;

e. the R3 metal liner was improperly promoted, marketed and sold in violation of the FDCA;

f. the R3 metal liner was improperly promoted, marketed and sold for use in applications other than the BHR System for which it was approved in violation of the FDCA and FDA regulations;

g. the R3 metal liner was improperly promoted, marketed and sold for use in combination with the R3 acetabular system, in violation of the FDCA and FDA regulations;

h. the R3 metal liner was improperly promoted, marketed and sold after Defendant withheld from and misrepresented to the FDA information that was material and relevant to the performance of the liner especially when used in combination with the R3 acetabular component and/or a cobalt and chrome femoral head;

i. the R3 metal liner was improperly promoted, marketed and sold after Defendants withheld from and misrepresented to the FDA information that resulted in inadequate warnings and/or instructions being approved by the FDA;

j. the R3 metal liner was improperly promoted, marketed and sold in violation of the FDCA and FDA regulations, including, but not limited to, FDCA section 501(f)(1)(B), 21 U.S.C. § 351(f)(1)(B), 21 U.S.C. §§ 331(b), 352(q), FDCA section 520(g), 21 U.S.C. § 360j(e)(g), FDCA section 510(k), 21 U.S.C. § 360(e)(k), 21 CFR 807.81(a)(3)(ii), 21 U.S.C. §§ 331(b), 352(q), and/or 21 CFR § 820 *et. seq.*;

k. the R3 liner was improperly misbranded, promoted, marketed, and sold to be used in applications other than with the BHR System and introduced into interstate commerce with major changes or modifications to its original use in violation of FDCA section 510(k), 21 U.S.C. § 360(e)(k), and/or 21 CFR 807.81(a)(3)(ii);

l. the R3 metal liner was improperly promoted, marketed and sold after Defendant failed to report to the FDA relevant adverse health consequences of the R3 metal liner of which it became aware after obtaining approval for its use with the BHR System;

m. the R3 metal liner was improperly promoted, marketed and sold after Defendant failed to comply with the FDAs premarket approval's monitoring and reporting requirements for reporting adverse outcomes caused by the R3 metal acetabular liner;

n. the R3 metal liner was improperly marketed and sold after Defendants failed to comply with the FDAs post-marketing surveillance obligations regarding the safety and efficacy of the R3 metal acetabular liner.

30. Plaintiff and her physician used the R3 device and its component parts in a way that was foreseeable to Defendant and as directed by Defendant, even though the metal liner was not

approved by the FDA to be used with the other R3 component parts.

31. At all times material to this Complaint, the unapproved and recalled R3 system and its component parts were defective, and Defendant knew that it was to be used by the user without inspection for defects contained therein.

32. At the time that the device and its component parts were designed and manufactured, there were safer alternative designs that would have alleviated the defects stated above and would have prevented the risk of injury without substantially impairing the device's utility. These safer alternative designs, including the less expensive cross-linked polyethylene liner that was originally were economically and technologically feasible by the application of existing or reasonably achievable scientific knowledge.

33. As a direct and proximate result of the above defects and unreasonably dangerous conditions, Plaintiff suffered (1) two revision surgeries and is at an increased risk for complications in the future, (2) permanent scarring and deformity, (3) physical pain, mental suffering, and mental anguish during and after the revision surgery which he will continue to suffer for the foreseeable future, (4) he has incurred and will continue to incur hospital, nursing, rehabilitation, and other medical bills and expenses, (5) he suffered a loss of her enjoyment of life, and (6) he has been caused to be permanently unable to pursue her normal and usual activities.

34. This cause of action is based in part on the contention that Smith & Nephew's actions violated state statutes and common laws, which constitute an independent and parallel violation of federal safety statutes and regulations as to the optional metal liner, as well as the conditions established in the PMA Approval Order for the optional metal liner with which Defendant agreed to comply to obtain premarket approval of the device.

35. Plaintiff also brings strict liability claims related to the premature failure of the other components in the R3 acetabular system, including the cup and femoral head, which are not subject to PMA protections but are instead products approved by the FDA via the 510(k) process. On information and belief, these all-metal components are the primary source of the R3 system's high failure rate, because they articulate against each other and general metal ion particles that cause tissue and bone destructions, and ultimately a revision surgery.

COUNT TWO: NEGLIGENCE

36. Plaintiff reasserts, realleges and incorporates all other paragraphs in the Complaint as if fully set out herein.

37. This count is brought against the Defendant pursuant to the Maryland common law tort of negligence, and is based in part on the contention that Smith & Nephew's actions violated Maryland state statutes and common laws, which constitute an independent and parallel violation of federal safety statutes and regulations as to the optional metal liner, as well as the conditions established in the PMA Approval Order for the optional metal liner with which Defendant agreed to comply to obtain premarket approval of the device.

38. Smith & Nephew negligently misrepresented to Plaintiff, the medical community and the general public that the metal-on-metal R3 system was safe. Any statements it made outside the FDA approved labeling for the optional metal liner and are not subject to express or implied preemption, because Smith & Nephew had a duty to be truthful in its communications and this duty exists outside the framework for the PMA approval. Any such statements Smith & Nephew made about the other R3 device components, including the cup and femoral head and stem, also escape preemption, because those components were approved through the 510(k) process.

39. Smith & Nephew negligently designed, manufactured, tested, inspected, assembled, imported, promoted, marketed, distributed, and/or sold the components in the R3 acetabular system for the reasons stated above. Smith & Nephew knew, or in the exercise of reasonable care should have known, that the device was defective and unreasonably dangerous due to its high rate of failure, its metal-on-metal design, its propensity for metal ion release into patients' hip joints, and numerous other reasons. For example, Smith & Nephew's competitors, including DePuy and Zimmer, recalled their metal-on-metal hip systems years before the R3 liner was finally recalled and pulled from the U.S. market in June 2012.

39. Smith & Nephew negligently designed, manufactured, tested, inspected, assembled, imported, promoted, marketed, distributed, and/or sold the R3 metal liner implanted into Plaintiff. The company negligently promoted, marketed, distributed and/or sold the R3 metal liner for use in applications other than the BHR System for which it was approved, including the R3 acetabular system, in violation of the FDCA and FDA regulations. Smith & Nephew knew, or in the exercise of reasonable care should have known, that the R3 metal liner was defective and unreasonably dangerous.

40. The initial approval for the metal liner was included in PMA Supplement P040033/S006. The liner was made available in nine sizes, all of them specifically intended for use in BHR femoral heads ranging from 38 mm to 54 mm. The liner material was cobalt chrome allow, ASTM F75 and ISO 5832-4. The design team included Dr. Robert Barrack, Dr. John Masonis, Dr. Wayne Golden, Dr. Richard Kyle, Dr. Michael Ries, and Dr. Henrik Malchau. The design team and Smith & Nephew created a visual depiction showing how to insert the metal liner in a patient's body as part of the BHR system, but they didn't show doctors how to insert the liner as part of the R3 total hip arthroplasty system because that configuration was not approved by

FDA. They also failed to warn patients about potential contraindications and risks for the metal liner in the R3 system, because the only approved use for the liner was with the BHR system.

41. Smith & Nephew's responsibilities did not end with the FDA's clearance of the metal liner as an extension to the previously approved BHR system. For example, Smith & Nephew expressly agreed to fulfill numerous post-approval obligations when it received conditional approval for the BHR System in 2006, and later for the resurfacing metal liner. Post-approval responsibilities also arose by operation of law from the Federal Statutes and Regulations that govern a device manufacturer's conduct in a case like this, whether by virtue of a Premarket Approval ("PMA") or a 510(k) clearance. Specifically, as a Class III device, the resurfacing metal liner was a BHR component subject to an express prohibition against any deviations from the approved specifications. See 21 U.S.C. 360(e).

42. On information and belief, Smith & Nephew never included the R3 metal liner in any of the post-approval clinical studies or adverse event reporting for the BHR system, as it was required to do under the PMA. For example, in its 2010 and 2011 annual reports to the FDA, Smith & Nephew did not mention any joint registries or clinical studies showing data for the R3 metal liner, and it did not mention adverse event reports or scientific literature about the R3 metal liner, even though it was part of the BHR system. The explanation for this omission is simple: Smith & Nephew never intended to use the R3 metal liner with the BHR system, but instead used the BHR approval as a short-cut because the FDA did not allow the metal liner to be used with the other components in the different R3 acetabular system.

43. After obtaining FDA Approval, Class III medical device manufacturers must also comply with Current Good Manufacturing Practices ("CGMPs") that are intended to ensure that finished devices are safe and effective. A medical device manufacturer's required adherence to

CGMPs does not end once a PMA is granted. See 21 C.F.R. sec. 820 et. seq. The Current Good Manufacturing Practices that apply to PMA devices also apply to devices that are grandfathered in to our country through the 510 (k) loophole described above. In addition, Smith & Nephew agreed to numerous other controls that applied to their pre- and post-market conduct, including Design Controls, Good Manufacturing, and recognized international consensus standards. Other obligations also arose by virtue of PMA or 510(k) clearance, and both sets of regulations apply when components from multiple devices are combined, as in Plaintiff's case. *See* 21 C.F.R. sec. 821 *et. seq*. and 21 C.F.R. sec. 822 *et. Seq*

44. During Plaintiff's surgery, Smith & Nephew negligently selected and directed that Plaintiff's implant the device and its component parts. Smith & Nephew also negligently failed to warn Plaintiff's surgeons of the defects stated above and also negligently failed to instruct them of the dangers associated with using the device and its component parts in an off-label surgery.

45. All of the foregoing negligent conduct of Smith & Nephew was the direct and proximate cause of the injuries and damages suffered by Plaintiff. These injuries and damages could have been prevented if Smith & Nephew had acted with reasonable care.

46. Smith & Nephew is vicariously liable for the torts committed by their employees and agents, including marketing and sales representatives, in the course and scope of their employment under the doctrine of respondeat superior.

COUNT THREE: BREACH OF IMPLIED WARRANTY

47. Plaintiff reasserts, realleges and incorporates all other paragraphs in the Complaint as if fully set out herein.

48. Smith & Nephew impliedly warranted that the device was reasonably fit and suitable for the purposes for which it was intended to be used, was free of defects, and was of

merchantable quality.

49. Smith & Nephew impliedly warranted that the R3 acetabular component, metal liner, cobalt chrome femoral head and femoral head sleeve implanted into Plaintiff were reasonably fit and suitable for the purposes for which it was intended to be used, free of defects and were of merchantable quality.

50. Smith & Nephew impliedly warranted that the R3 metal liner and other component parts were reasonably fit and suitable for the purposes for which they were intended to be used, was free of defects, and were of merchantable quality. Specifically, Smith & Nephew warranted in its public communications, press releases, and sales tactics that the metal liner was a safe and effective option for the R3 system, even though it was only approved for use with the BHR system, and even though no surgical technique or contraindications were available for the metal liner when used in the R3 system.

51. Smith & Nephew breached said warranties.

52. Plaintiff and her physicians were and are unskilled in the research, design, and manufacture of hip implant devices, and they reasonably relied entirely on the skill, judgment, and implied warranties of Smith & Nephew in using the device and its component parts.

53. The breach of warranty by Smith & Nephew was the direct and proximate cause of the injuries and damages suffered by Plaintiff. These injuries and damages could have been prevented if Smith & Nephew had not breached its warranty.

COUNT FIVE: BREACH OF EXPRESS WARRANTY

54. Plaintiff reasserts, realleges and incorporates all other paragraphs in the Complaint as if fully set out herein.

55. At all times material to this Complaint, Smith & Nephew, both orally and in writing,

warranted that the R3 acetabular system device was safe, effective, fit, and proper for its intended use.

56. At all times material to this Complaint, Smith & Nephew, by and through statements made by its employees, agents, and representatives, orally and in writing, warranted that the R3 acetabular component, cobalt chrome femoral head and femoral head sleeve were safe, effective, fit, and proper for their intended use.

57. At all times material to this Complaint, Smith & Nephew, by and through statements made by Smith & Nephew and/or its employees, agents, and representatives, orally and in writing, warranted that the R3 metal liner was safe, effective, fit, and proper for its intended use. These statements extend to the metal liner being used in the R3 system, even though it was only approved for use with the BHR system. For example, in its 2008 "pocket guide" for U.S. surgeons, Smith & Nephew stated that the metal liners were available for cup sizes 50 mm to 68 mm, and were to be used only with BHR heads.

58. Likewise, in its instructions for metal liner insertion, Smith & Nephew stated that the liner could only be used with BHR femoral heads. But it contradicted that position by publishing other statements suggesting that the R3 metal liner was "compatible" with the R3 system generally, and as the designer of both the BHR and R3 systems the company was aware that the 510(k) approved cobalt-chrome modular head was designed to be compatible with both the BHR system or the R3 system, when paired with an R3 STIKTITE coated shell and a traditional femoral stem. Surgical technique guides and brochures for the R3 system thus offered photographs of the metal liner, but no mention about how to implant the liner with an R3 shell and modular head. Furthermore, because the only approved uses for the R3 system included a polyethylene or ceramic liner, Smith & Nephew did not include any of the warning language about the risk of

pseudotumors, metal ion release, metal debris, or other symptoms of metallosis in the R3 warnings and contraindications section of its surgical technique guide.

59. In utilizing the device and its component parts, Plaintiff and her physicians relied on the skill, judgment, representations, and foregoing express warranties of Smith & Nephew.

60. Said warranties and representations were false.

61. The breach of warranty by Smith & Nephew was the direct and proximate cause of the injuries and damages suffered by Plaintiff. These injuries and damages could have been prevented if Smith & Nephew had not breached its warranty.

COUNT SIX: FRAUD

62. Plaintiff reasserts, realleges and incorporates all other paragraphs in the Complaint as if fully set out herein.

63. Smith & Nephew intentionally, recklessly, and/or mistakenly made false statements of material facts about the device and its component parts to Plaintiff, Plaintiff's physicians, and the general public as described herein. Specifically, Smith & Nephew and its employees, agents and representatives:

a. falsely misbranded, promoted and marketed the R3 metal liner as being approved for use in applications other than the BHR System, including the R3 acetabular system;

b. made false representations that the component parts of the device were compatible and would combine to make a high-quality, safe and effective hip replacement system; and,

c. falsely represented that the R3 metal liner was compatible, safe and effective when used as part of a total hip replacement device in combination with the R3 acetabular component and cobalt chrome femoral heads and sleeves.

64. Smith & Nephew and its employees, agents and representatives made such statements knowing they were false and/or without knowing whether they were true intending that

Plaintiff, Plaintiff's physicians, and the general public rely on the statements.

65. Plaintiff's healthcare providers reasonably relied on the statement(s) and acted on the statement(s) by implanting the device and its component parts into Plaintiff.

66. Smith & Nephew and its employees, agents and representatives also hid and withheld materials facts about the device and its component parts from Plaintiff's, Plaintiff's physicians, and the general public as described herein. Specifically, Smith & Nephew and its employees, agents and representatives:

a. hid/withheld the fact that the R3 metal liner was only approved and intended for use in the BHR System;

b. hid/withheld the fact that the R3 metal liner was not approved or intended for use in combination with the R3 acetabular component and cobalt chrome femoral heads and sleeves;

c. hid/withheld the fact that the component parts of the device were incompatible and would combine to make a dangerous, unsafe and ineffective hip replacement system; and,

d. hid/withheld the known dangers and risks of using the R3 acetabular component, cobalt chrome femoral head and femoral head sleeve in combination with the R3 metal liner.

67. Plaintiff and Plaintiff's physicians did not know of such material facts and acted by implanting the device and its component parts into Plaintiff.

68. As a direct result of the fraudulent conduct of Smith & Nephew and its employees, agents and representatives, Plaintiff suffered damages as set forth above.

WHEREFORE, PREMISES CONSIDERED, Plaintiff respectfully requests this Court to enter judgment in her favor and against the Defendant, Smith & Nephew, Inc. Plaintiff requests an award of compensatory and punitive damages in an amount determined by a jury, together with interest, costs, and all other relief which may be just and proper.

Dated: August 18, 2018

Respectfully submitted,

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